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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,313	12/29/2000	Gerardo Castillo	PROTEO.P16	1184

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ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 01/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/753,313	Applicant(s) CHOI ET AL.	
	Examin r Shaojia A. Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears n the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-5, 10-13 and 15-27* is/are pending in the application.

4a) Of the above claim(s) *24-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,5,10-13 and 15-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 13, 2002 has been entered.

This Office Action is a response to Applicant's request for continued examination (RCE) filed November 13, 2002 in Paper No. 9, and amendment and response to the Final Office Action (mailed June 5, 2002), filed November 13, 2002 in Paper No. 10 wherein claims 1-3, 6-7, and 14 are cancelled, and claims 4-5, 10-13 and 15-21 have been amended, and claims 22-27 are newly submitted. Currently, claims 4-5, 10-13 and 15-27 are pending in this application.

It is noted that the newly claims 24-27 are drawn to a pharmaceutical composition herein that is independent or distinct from the invention originally claimed, which is directed to a method for the treatment herein.

According to MPEP § 819, the general policy of the Office is not to permit the applicant to shift to claiming another invention after an election is once made and/or an action given on the merits. The Office is also not to permit the applicant to shift to claim another invention in RCE.

In the instant case, the original invention (claims 1-21) is drawn to a method for the treatment, whereas the invention of newly submitted claims 24-27 is drawn to a composition comprising specified components herein. The original invention and the newly claimed invention are separate and distinct, related as process of use and product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, for example, a statin may be used in a method for the treatment of an amyloidosis or amyloid formation, deposition, accumulation in a mammal.

Thus, the original invention and the newly claimed invention are seen to be separate and distinct inventions. Note that a reference to the composition herein would not necessarily be a reference to the method of treatment herein under 35 USC 103. The composition and method herein have separate consideration as to patentability.

Therefore, claims 24-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant's amendment amending claims 4-5, 10-13 and 15-21, filed November 13, 2002 in Paper No. 10 with respect to the rejection made under 35 U.S.C. 112 first paragraph for lack of scope of enablement in claims 1-7 and 10-21 of record stated in the Office Action dated June 5, 2002 has been fully considered and is found persuasive

to remove the rejection since the expressions "their derivatives" or "well known derivatives of any of the foregoing substances" have been removed. Therefore, the said rejection is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-5,and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expressions "other amyloidoses" in claim 4 render claims 4-5 and 10 indefinite. The expressions "other amyloidoses" are not defined in the claim and specification. The scope of the claim is unclear as to as to the method encompassed thereby.

Claim 10 recites the limitation "plant materials" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Applicant's remarks regarding the expressions "age-associated" and "age-related" brain or cognitive disorders in the rejection of claim 18 in the previous Office Action June 5, 2002 have been fully considered and found persuasive.

Applicant's amendment canceling 1-3 and amending claims 4-5 and 10-12 filed November 13, 2002 in Paper No. 10 with respect to the rejection made under 35 U.S.C. 112, second paragraph, for the indefinite expression, " standardized green tea

extract" have been considered and found persuasive since this expression has been removed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22-23 provide for the use of a source of green tea..., but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 22-23 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-5, 10-12, 19 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to the methods for **preventing** amyloid fibril formation, deposition, accumulation or aggregation in Alzheimer's disease. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Nature of the invention: The instant invention pertains to the methods for preventing amyloid fibril formation, deposition, accumulation or aggregation in Alzheimer's disease.

The state of the prior art: The skilled artisan would view that the treatment to prevent amyloid fibril formation, deposition, accumulation or aggregation in Alzheimer's disease is highly unlikely.

The predictability or lack thereof in the art: The skilled artisan would view that the treatment to prevent amyloid fibril formation, deposition, accumulation or aggregation in Alzheimer's disease is highly unpredictable.

The presence or absence of working examples: In the instant case, **no** working examples are presented in the specification as filed showing how to prevent amyloid fibril formation, deposition, accumulation or aggregation in Alzheimer's disease.

Therefore, in view of the *Wands* factors, as discussed above, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art, Applicants fail to provide information sufficient to practice the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-5, 10-13 and 15-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Castillo et al. (WO 98/51302 of record).

Castillo et al. discloses that Uncaria tomentosa plants and their extracts (known containing common flavanols such as catechins including epicatechin, and gallocatechin), are useful in methods of treatment, prevention, or management of an amyloidosis or amyloid formation, deposition, accurmulation in a mammal. See abstract, pages 1-3 specially page 2 lines 23-24, page 3 lines21-23 and 31-33, page 6 lines 30-31, page 9 lines 12-14, page 12 lines 12-14, and claim 6. Thus, Castillo et al. anticipates claims 4-5, 10-13 and 15-21.

Applicant's remarks filed November 13, 2002 in Paper No. 10 with respect to this rejection in the previous Office Action dated June 5, 2002 have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art because Uncaria tomentosa plants and their extracts are well known to contain common flavanols such as catechin, epicatechin, and gallocatechin in the art.

Claims 4-5, 10-13 and 15-21 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 10245342 (of record).

JP 10245342 discloses that tea polyphenols (known catechins including epicatechin, and gallocatechin in green tea leaf extract) is useful for reducing an amyloidosis or amyloid formation, deposition, accurmulation in a mammal. See abstract. JP 10245342's teaching is inherent in the instant claimed methods of treatment, prevention, or management of an amyloidosis or amyloid formation, deposition,

accurmulation in a mammal. See *Ex parte Novitski*, 26 USPQ 2d 1389. Thus, JP 10245342 anticipates claims 4-5, 10-13 and 15-21.

Applicant's remarks filed on November 13, 2002 in Paper No. 10 with respect to this rejection made under 35 U.S.C. 102(b) of record stated in the previous Office Action have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art for the following reasons.

Applicant asserts that Mitsui (JP 10245342) teaches narrowly only the nerve cell toxicity caused by beta-amyloid protein by employing the same compounds, tea polyphenols. Applicant's arguments are not found persuasive. As discussed in the 102(b) rejection in the previous Office Action, Mitsui's method employing the same compounds in a method of reducing the toxicity of beta-amyloid protein against nerve cells in a mammal inherently treats prevent or manage the same living animal for an amyloidosis or amyloid formation, deposition, accurmulation in a mammal, as claimed herein, since Mitsui's method steps are same as the instant method steps. See *Ex parte Novitski*, 26 USPQ 2d 1389. See also MPEP § 2112.01 with regard to inherency as it related to the claimed invention herein.

Moreover, the mechanism of action of a treatment does not have a bearing on the patentability of the invention if the method steps are already known even though applicant has proposed or claimed the mechanism. Applicant's recitation of a new mechanism of action for the prior art method will not, by itself, distinguish the instant claims over the prior art teaching the same or nearly the same method steps. Mere

recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201 USPQ 658 (CCPA 1979).

Thus, Mitsui anticipates the claimed invention.

Claims 4-5, 10-13 and 15-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Shin-Ya et al., (of record).

Shin-Ya et al. discloses that catechins (epicatechin is a known catechin), a known ingredient of green tea, black tea, or other natural sources is useful for against beta-amyloid toxicity in a mammal. See abstract. Shin-Ya's teaching is inherent in the instant claimed methods of treatment, prevention, or management of an amyloidosis or amyloid formation, deposition, accurmulation such as Alzheimer's disease in a mammal. See *Ex parte Novitski*, 26 USPQ 2d 1389. Thus, Shin-Ya et al. anticipates claims 4-5, 10-13 and 15-21.

Applicant's remarks filed November 13, 2002 in Paper No. 10 with respect to this rejection in the previous Office Action dated June 5, 2002 have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art because epicatechin is a known catechin to those skilled in the art. Applicant's admission regarding the prior art in the specification also teaches that Catechin, epicatechin, galocatechin, and epigalocatechin are known to be catechins, obtained from green teas. See the instant specification at page 5 lines 13-16.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
January 21, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER

1/21/03